

REMARKS

Claims 1-83 were previously submitted for examination. Claims 1-9 and 60-80 were previously withdrawn from consideration due to a restriction requirement, claims 19-21 and 40-57 were previously canceled, and claims 81-96 were previously added. In the November 21, 2006 telephonic interview, the Examiner indicated that the restriction requirement on claims 1-9 is withdrawn. Claims 60-80 have been cancelled, claims 1-3, 5, 8-10, 16, 18, 22, 23, 31, 32, 36, 59, 81, 84, 87-91 and 96 have amended and claims 97-99 have been added by the present amendment. Therefore, claims 1-18, 22-39, 58, 59 and 81-99 are currently under consideration.

The phrase “non-whole PTH fragment” in claims 1, 8-10, 22, 23, 59, 84 and 87-90 have been replaced with “non-(1-84) or non-(1-86) PTH fragment.” Support for this amendment can be found throughout the present application as originally filed and, *inter alia*, in paragraph [0055] of the present specification which states that “whole parathyroid hormone (PTH)” or “wPTH” refers to the complete molecule of PTH, and in paragraphs [0099] to [00105] of the present specification which show that the complete molecules of PTH from various mammalian species have 84 or 86 amino acid residues. Therefore, “non-whole PTH fragment” is synonymous with “non-(1-84) or non-(1-86) PTH fragment” and this amendment does not change the scope of the amended claims. Additional support for reciting “non-(1-84) PTH fragment” can be found in paragraphs [0004], [0007], [0047], [0049], [00145], [00147], [00159], [00160], and Figures 18 and 20.

Claims 2 and 16 have been amended to clarify that the recited monoclonal antibody, polyclonal antibody or antibody fragment specifically binds to whole PTH. Support for this amendment can be found throughout the present application as originally filed and, *inter alia*, in paragraph [0071] of the present specification which states that the term “specifically binds” refers to the specificity of an antibody such that it preferentially binds to a defined target. In addition, as shown in paragraphs [0040], [0043], [00132] and [00154], and in Figures 11 and 14, an exemplary antibody preferentially binds to whole PTH in the presence of a large excess amount of an exemplary “non-(1-84) PTH fragment,” PTH (7-84) fragment. These data show that the exemplary antibody specifically binds to whole PTH.

Claim 3 has been amended to add certain PTH epitopes that have been deleted from the original claim 5. Support for this amendment can be found throughout the present application as originally filed and, *inter alia*, in original claim 5.

Claim 5 has been amended to delete certain PTH epitopes from the original claim 5.

Claims 10, 18, 31, 32, 59, 81, 87 and 89 have been amended to recite the abbreviated name “PTH” instead of the full name “parathyroid hormone” for consistency.

Claim 36 has been amended to delete “to monitor bone disease or disorder related treatment” and new claim 97 has been added to recite “to monitor bone disease or disorder related treatment.” Both amended claim 36 and the new claim 97 find support throughout the present application as originally filed and, *inter alia*, in original claim 36.

Claims 91 and 96 have been amended to recite that the isolated antibody specifically binds to whole PTH. Support for this amendment can be found throughout the present application as originally filed and, *inter alia*, in paragraph [0071] of the present specification which states that the term “specifically binds” refers to the specificity of an antibody such that it preferentially binds to a defined target. In addition, as shown in paragraphs [0040], [0043], [00132] and [00154], and in Figures 11 and 14, an exemplary antibody preferentially binds to whole PTH in the presence of a large excess amount of an exemplary “non-(1-84) PTH fragment,” PTH (7-84) fragment. These data show that the exemplary antibody specifically binds to whole PTH.

New claim 98 depends on claim 8 and recites a subset of PTH epitopes recited in claim 8. New claim 98 finds support throughout the present application as originally filed and, *inter alia*, in original claim 8.

New claim 99 depends on claim 22 and recites a subset of PTH epitopes recited in claim 22. New claim 98 finds support throughout the present application as originally filed and, *inter alia*, in original claim 22.

Accordingly, the present amendments do not introduce any new matter into the present application.

Applicant's Statements of the Substances of the November 7, 2006 Interview

On November 7, 2006, Examiners Jacob Cheu, Long Le, Larry Helms, Inventor Thomas L. Cantor and the undersigned had an interview to discuss the various outstanding issues for the present application. Applicant and the undersigned greatly appreciate Examiners' granting the interview and discussing the various issues with Inventor Thomas L. Cantor and the undersigned. The following is a summary of the November 7, 2006 interview:

- Applicant presented experimental data to distinguish Colford et al. reference, particularly the experimental data indicating the difference between the antibodies in the instant invention and that of the Colford et al. with respect to the binding of the non-whole PTH fragment in the respective PTH assay.
- Applicant further distinguished the teachings of Rucinski et al. from the instant invention, particularly the fact that Rucinski et al do not teach the use of an antibody that avoids binding to a non-whole PTH fragment.

Applicant's Statements of the Substances of the November 21, 2006 Interview

On November 21, 2006, Examiners Jacob Cheu and the undersigned had a telephonic interview to discuss the various outstanding issues for the present application. Applicant and the undersigned greatly appreciate Examiners' granting the interview and discussing the various issues with the undersigned. The following is a summary of the November 21, 2006 interview and applicant's response to the Examiner's requests raised in the interview:

- The Examiner indicated that in order to place the present application into condition for allowance, terminal disclaimers as related to the two parent patents,

U.S. Patent Nos. 6,689,566 and 6,743,590, are required. Applicant filed the requested terminal disclaimers on November 21, 2006.

- The Examiner indicated that the restriction requirement on claims 1-9 is withdrawn. Applicant appreciates the withdraw and has changed the status of claims 1-9 accordingly.
- The Examiner requested the cancellation of claims 60-80. Applicant has changed the status of claims 60-80 accordingly.
- The Examiner requested the replacement of “non-whole PTH fragment” with “non-(1-84) or non-(1-86) PTH fragment” in various claims. Applicant has made such an amendment in claims 1, 8-10, 22, 23, 59, 84 and 87-90.
- The Examiner requested further clarification of the “antibody fragment” in claims 2 and 16. Claims 2 and 16 have been amended to clarify that the recited monoclonal antibody, polyclonal antibody or antibody fragment specifically binds to whole PTH.
- The Examiner requested the cancellation of claim 5. Applicant has placed certain PTH epitopes recited in claim 5 into the presently pending claim 3, kept a subset of PTH epitopes in the presently pending claim 5, and has deleted a majority of PTH epitopes recited previously.
- The Examiner requested that, to be consistent, abbreviated name “PTH” be used in certain places instead of the full name “parathyroid hormone.” Applicant has amended claims 10, 18, 31, 32, 59, 81, 87 and 89 to recite the abbreviated name “PTH” instead of the full name “parathyroid hormone.”
- The Examiner requested that claim 36 be separated into two claims. Applicant has deleted “to monitor bone disease or disorder related treatment” in presently

pending claim 36 and has added new claim 97 to recite “to monitor bone disease or disorder related treatment.”

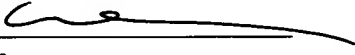
CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 53221-2000623. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: November 28, 2006

Respectfully submitted,

By 
Peng Chen
Registration No.: 43,543
MORRISON & FOERSTER LLP
12531 High Bluff Drive, Suite 100
San Diego, California 92130-2040
(858) 720-5117